

## REMARKS

### Summary of the Examiner's Actions

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Ciani *et al.*, U.S. Patent Number 4,140,127. Applicant acknowledges the rejection under 35 U.S.C. §102(b).

Claim 13 was rejected under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Barnes *et al.*, U.S. Patent Number 3,812,769. Applicant acknowledges the rejection under 35 U.S.C. §103(a).

Claims 2, 3, 14 and 15 were rejected under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Wu *et al.*, U.S. Patent Number 4,246,909, or in view of Ciani *et al.*, in view of Barnes *et al.*, in view of Wu *et al.* Applicant acknowledges the rejection under 35 U.S.C. §103(a).

Claims 4 and 16 were rejected under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Wu *et al.*, or in view of Ciani *et al.*, in view of Barnes *et al.*, in view of Wu *et al.*, as applied to Claims 2 and 13 above, and further in view of Poncy, U.S. Patent Number 4,165,000. Applicant acknowledges the rejection under 35 U.S.C. §103(a).

Claims 5 and 17 were rejected under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Poncy, or Ciani *et al.*, in view of Barnes *et al.*, in view of Poncy. Applicant acknowledges the rejection under 35 U.S.C. §103(a).

Claims 6 and 18 were rejected under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Gammons *et al.*, U.S. Patent Number 6,224,543, or Ciani *et al.*, in view of Barnes *et al.*, in view of Gammons *et al.* Applicant acknowledges the rejection under 35 U.S.C. §103(a).

Claim 7 was rejected under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Weaver, U.S. Patent Number 5,667,068. Applicant acknowledges the rejection under 35 U.S.C. §103(a).

Claims 8-10 were rejected under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Poncy and further in view of Wu *et al.* Applicant acknowledges the rejection under 35 U.S.C. §103(a).

Claim 11 was rejected under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Poncy and Wu *et al.*, and further in view of Gammons *et al.* Applicant acknowledges the rejection under 35 U.S.C. §103(a).

Claim 12 was rejected under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Poncy and Wu *et al.*, and further in view of Weaver. Applicant acknowledges the rejection under 35 U.S.C. §103(a).

#### **Interview with Examiner**

Applicant is appreciative of the Examiner granting a telephone interview with his legal representative, Jeffrey N. Cutler, on January 19, 2007. The substance of this response was provided for discussion, with the exception of the amendments to the claims. To that extent, it was discussed that the purpose of the present invention is to provide a probe cover that defines a double thickness at the throat such that as the probe end is inserted therein, the probe cover remains in place as it is inserted into a patient.

As discussed briefly in the interview, and as disclosed in the specification (see, for example, page 6, lines 20-23, and PRIOR ART FIGS. 1 and 2), the present invention is designed to eliminate the need for a retainer, such as a rubber band, to maintain the probe cover in place on the probe as it is inserted into the patient, thereby minimizing discomfort. This is accomplished by providing a double thickness of material at the throat of the probe cover.

As discussed with the Examiner, Claim 1 has been amended to include the limitations of Claim 2. Further, each of the independent claims has been amended to include language to the effect that the double thickness of material at the throat provides the resiliency required to maintain the probe cover on the probe without necessitating further retaining means. The Examiner indicated that language that might be considered functional would be acceptable if such language were useful to defining the scope of the invention.

It is respectfully submitted that with the amendment of Claims 1, 8 and 13, and the resulting cancellation of Claims 2 and 14, that the present application is in condition for allowance.

#### **Rejections under 35 U.S.C. §102(b)**

##### *1) The Law of Anticipation*

35 U.S.C. §102(b) states that "[a] person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. §102(b) (2000). Section 2131 of the Manual of Patent Examining Procedure summarizes the standards for anticipation under 35 U.S.C. §102(b) as articulated by the United States Court of Appeals for the Federal Circuit. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

2) *Claim 1*

Examiner's Rejection

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Cianci *et al.*, U.S. Patent Number 4,140,127. In support of the rejection, the Office Action states:

Cianci discloses a catheter sheath having a first panel member 48a and a second panel member 48b defining a tubular configuration, the first panel being folded over to form a double thickness, and the second panel being folded over to form a double thickness (Col. 3, lines 30-40). See Fig. 2. Cianci inherently discloses the steps of providing a first panel 28a and a second panel 28b and folding the panels and heat sealing the panels to each other. The claim 1 limitation of folding the panels prior to securement is considered to be a product by process limitation. These claims are not limited to the manipulations of the recited steps, only the structure implied but the steps. The patentability of a product does not depend on its method of production. See MPEP 2113.

Applicant's Argument

The prior similar rejection of Claim 13 has been withdrawn. Applicant is appreciative of such consideration. The rejection of Claim 1, however, remains substantially as stated in the prior Office Action. Applicant's prior remarks in response to this rejection are incorporated herein by reference.

In response to the Applicant's prior arguments, this Office Action further indicates that the "limitation of folding the panels prior to securement is considered to be a product by process limitation." Further, it is argued that "a product by process limitation ... does not give the claim patentability."

Applicant respectfully disagrees. While it is admitted that the process does not give the claim patentability, the product resulting from the process does. To this end, MPEP §2113 sets forth the rationale for determining whether a product-by-process claim is allowable. MPEP §2113 states in part:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The

patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) ...

Because the Office Action has indicated a *prima facie* case of unpatentability, the question becomes whether the product in the product-by-process claim is the same as or obvious from a product of the prior art. In determining this question, MPEP §2113 continues:

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)

Cianci *et al.*, disclose a sheath in which is disposed a catheter. The distal end of the sleeve is folded over after the manufacture of the sheath so that it can be unfolded once the catheter is placed. In contrast, in the present invention, the two panel members are each folded over *prior to securement* to each other. In so doing, the first end of each panel permanently defines a double thickness. As discussed previously, this construction provides several benefits. First, as disclosed in the specification in paragraph [0025], "[t]he construction of the first ends 128,138, namely by folding to provide a double thickness, furthers the ease of opening the first end opening 114 in the described manner."

The double thickness of the first end further assists in the restriction of the throat over the probe as it is inserted, thereby obviating the need for a retainer such as a rubber band, as discussed. Referring to paragraph [0006], a typical sheath such as that disclosed by Cianci *et al.*, is fabricated from a single thickness of film. This is

insufficient to retain the sheath on the probe without assistance, such as a rubber band as illustrated in the prior art Figs. 1 and 2 of the present application. In the present invention, because the first end of the two panels are folded over to define the double thickness prior to securement of the two panels, the overlapped portions are permanently formed into double layers, thereby providing the strength required to be retained on a probe unassisted.

Claim 1 of the present application sets forth in part:

... said first panel first end being folded over *prior to securement to said second panel member* to define a double thickness, and said second panel member first end being folded over *prior to securement to said first panel member* to define a double thickness

It is respectfully submitted that one skilled in the art would recognize that such would render the double thickness portions permanently secured in that manner. Once bonded, the double thickness portions could not be unfolded. On the contrary, it is clear that the distal end of the sheath is folded over only after the sheath is formed, and is unfolded as a step in its use. Accordingly, it is respectfully submitted that Ciani *et al.*, teach away from the present invention and, at the very least, do not anticipate the permanent securement of the distal end of the sheath in the folded configuration.

Moreover, the structure implied by the process steps is patentably distinct from the cited prior art for those reasons stated above. Thus, even though the device of Claim 1 is a product-by-process as set forth, the product is patentably distinct from the prior art of record in that the product as claimed is structurally unique as compared to that of Ciani *et al.*

Notwithstanding the noted allowability of Claim 1 as originally presented, Claim 1 has been amended to include the limitations of Claim 2, that a throat is defined proximate the cover first end and that the throat is adapted to closely receive a distal end of the medical probe. Claim 1 has further been amended to include the limitations

that the throat is defined within a region where each of the first and second panel members defines a double thickness in order to provide sufficient resiliency to maintain the cover on the distal end of the medical probe without necessitating further retaining means. It is respectfully submitted that these limitations are not disclosed, anticipated or made obvious by the prior art of record.

In view of the amendment of Claim 1, Claim 2 has been cancelled, without prejudice.

Accordingly, it is respectfully submitted that the rejection of Claim 1 under 35 U.S.C. §102(b) has been overcome. Having no further objection to or rejection of Claim 1, it is respectfully submitted that such claim is in condition for allowance. Further, it is deemed that Claims 3-12, each depending from Claim 1, are each in condition for allowance as depending from an allowable base claim.

#### **Rejections under 35 U.S.C. §103(a)**

##### *1) The Law of Obviousness*

35 U.S.C. §103(a) reads:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. §103(a) (2004).

A rejection under 35 U.S.C. §103(a) must be supported by a *prima facie* case of obviousness. MPEP § 2142. Section 2143 of the Manual of Patent Examining Procedure summarizes the standards for a *prima facie* case of obviousness under 35 U.S.C. §103. The first element is that “there must be some suggestion or motivation, either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings.” MPEP § 2143. The second element is that “there must be a reasonable expectation of success.” *Id.* The third element is that “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” *Id.* The expectation of success and the motivation to combine the references “must both be found in the prior art, not in the applicants disclosure.” *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

“There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.” *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper); see MPEP § 2143.01. “Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight.” *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

The standard of review applied to findings of fact is the “substantial evidence” standard under the Administrative Procedure Act (APA). See *In re Gartside*, 203 F.3d 1305,1315,53 U.S.P.Q.2d 1769,1775 (Fed. Cir. 2000); see also MPEP 2144.03, pg. 2100-136, 8th ed., rev. 2. There must be some form of evidence in the record to support an assertion of common knowledge. See *In re Lee*, 277 F.3d 1338, 1344-45, 61 U.S.P.Q.2d 1430, 1434-35 (Fed. Cir. 2002); *In re Zurko*, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001); see also MPEP 2144.03, pg. 2100-137, 8th ed., rev. 2. “With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience -- or on its assessment of what would be basic knowledge or common sense. Rather, the Board



must point to some concrete evidence in the record in support of these findings." *In re Zurko*, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001).

2) *Claim 13*

Examiner's Rejection

Claim 13 was rejected under 35 U.S.C. §103(a) as being obvious under *Cianci et al.*, in view of *Barnes et al.*, U.S. Patent Number 3,812,769. In support of the rejection, the Office Action states:

Claim 13 differs from the teachings of *Cianci* in calling for the step of folding the first and second panels before securing the members together. *Barnes* teaches a method of manufacturing a two ply bag including the steps of first folding the first and second panels then sealing them together (Col. 1, line 65 - Col. 2, line 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of *Cianci* to include folding the panels before securing them as taught by *Barnes* as a low cost and efficient way to make a two-ply member.

Applicant's Argument

This rejection is new relative to the prior Office Action. The newly cited *Barnes et al.*, patent teaches, as the Office Action states, a method for manufacturing plastic bags. However, *Barnes et al.*, is specifically directed to a valve bag for packaging materials such as fertilizers and cement (see *Barnes et al.*, col. 2, lines 34-35, as defined at col. 1, lines 10-11). *Barnes et al.*, disclose a two-ply construction, with both plies folded over each other (see FIGS. 2 and 3) and secured along a portion thereof to form a valve opening 6. (*id.*, col. 2, lines 42-44) While not explicitly stated, in order to create the valve, both plies must be folded over each other. Otherwise, an opening would be formed at that edge of portion 4. Thus, the manner in which the plies are folded is critical in order to achieve the invention set forth by *Barnes et al.*

In the present invention, the object is not to seal the inner contents of the medical probe cover, but to provide a means by which the medical probe cover may be inverted

to reveal a sterile probe cover surface. (see Specification, paragraph [0027]) If the manufacture of the probe cover of the present invention were to include the step of folding the first and second panel members respective first ends over each other, which is critical to Barnes *et al.*, then the present invention would not be capable of being inverted, which is correspondingly critical to the present invention. Thus, as claimed in Claim 13, at least the steps of (b) folding said first panel member first end under said first panel member; and (d) folding said second panel member first end over said second panel member are not taught by Barnes *et al.* On the contrary, it is respectfully submitted that Barnes *et al.*, teach away from such limitations. The Federal Circuit has addressed this issue, *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984), reaching the conclusion that if the “proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification,” as noted in MPEP §2143.01(V).

In the *In re Gordon* case, the Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. However, the court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose. Similarly, in the present application, it is respectfully submitted that to modify the Cianci *et al.*, by the teachings of Barnes *et al.*, would render both inoperable for their intended purposes.

Referring back to MPEP §2143, it is respectfully submitted that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the Cianci *et al.*, by the teachings of Barnes *et al.*, or to combine such reference teachings in order to accomplish the present invention. Even if there were some motivation, there is no reasonable expectation of success, as the method of folding the Barnes *et al.*, device, were it to be employed in such combination, would render one end of the resulting device sealed. Because neither of the references discloses at least the limitations as set forth above, it is

further submitted that the third element that “the prior art reference (or references when combined) must teach or suggest all the claim limitations” is also not met.

Accordingly, in view of the distinguishing remarks set forth above, it is respectfully submitted that Claim 13 as originally presented is allowable under 35 U.S.C. §103(a).

Notwithstanding the noted allowability of Claim 13, such has been amended similarly to that stated above with respect to the amendments of Claim 1. Specifically, Claim 13 has been amended to include the limitation of the step of securing said first panel member and said second panel member includes the step of defining a throat proximate the cover first end and within a region in which the first and second panel members define a double thickness, that the throat is adapted to closely receive a distal end of the medical probe, and that the double thickness of each of the first and second panel members provides sufficient resiliency to maintain the cover on the distal end of the medical probe without necessitating further retaining means. As above, it is respectfully submitted that these limitations are not disclosed, anticipated or made obvious by the prior art of record.

In view of the amendment of Claim 13, Claim 14 has been cancelled, without prejudice.

Accordingly, it is respectfully submitted that the rejection of Claim 13 under 35 U.S.C. §103(a) has been overcome. Having no further objection to or rejection of Claim 13, it is respectfully submitted that such claim is in condition for allowance. Further, Claims 15-18 are deemed allowable as depending from an allowable base claim.

3) *Claims 2, 3, 14 and 15*

Examiner's Rejection

Claims 2, 3, 14 and 15 were rejected under 35 U.S.C. §103(a) as being obvious under *Cianci et al.*, in view of *Wu et al.*, U.S. Patent Number 4,246,909, or in view of *Cianci et al.*, in view of *Barnes et al.*, in view of *Wu et al.* In support of the rejection, the Office Action states:

Claim 2 differs from *Cianci* in calling for the cover to further comprise a throat. Claim 3 differs in calling for the width of the throat to be less than [sic] one half of the circumference of the medical probe. Claims 14 and 15 differ in calling for the step of providing a throat with the specified circumference. *Wu* teaches a cover 10 for a medical probe having a throat 37 that has been heat sealed with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of *Cianci* to have a throat of less than one half the circumference of the probe as taught by *Wu* so that the cover cannot inadvertently slide off of the probe.

Applicant's Argument

The prior rejection has been restated, and an additional combination of reference, to further include *Barnes et al.*, has been cited. While an additional reference has been cited, the rationale is identical to that of the previous Office Action. There has been no rationale provided for the newly cited prior art. Accordingly, the Applicant's prior response is repeated herein by reference.

Notwithstanding the lack of specific rationale in making the above combination of references, it is assumed that the intent of the Office Action was to combine the step of folding the two-ply construction over itself as taught by *Barnes et al.*, prior to sealing thereof. Applicant's remarks above with respect to *Barnes et al.*, are incorporated herein by reference.

It is respectfully submitted that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the Cianci *et al.*, by the teachings of Barnes *et al.*, and Wu *et al.*, or to combine such reference teachings in order to accomplish the present invention. Even if there were some motivation, there is no reasonable expectation of success in making such combination to accomplish the present invention. Because neither of the references discloses at least the limitations as set forth above, it is further submitted that the prior art reference (or references when combined) fail to teach or suggest all the claim limitations.

Further, in view of the deemed allowability of independent Claims 1 and 13 above, it is deemed that Claims 2 and 3 are allowable as depending from allowable base Claim 1, and that Claims 14 and 15 are allowable as depending from allowable base Claim 13.

In response to the previous Office Action, Applicant noted that Wu *et al.*, teach the receipt of a catheter **11** in an opening **37**, the catheter being smaller than the opening such that the catheter may slide freely therein. Further, it was noted that in order to prevent the removal of the catheter, the catheter defines a bulbous end **20** dimensioned larger than the opening, and that the bulbous end cannot be received within the opening. In contrast, as claimed in Claim 2 of the present application, the present invention includes a throat “adapted to closely receive a distal end of the medical probe.” Then, as claimed in Claim 3, the throat is further adapted to define “a width adapted to be less than one-half the circumference of the medical probe distal end.” Similar limitations are set forth in Claims 14 and 15, respectively. Thus, the conclusion was drawn that there is no motivation for combining the prior art references to accomplish the present invention, that there is no reasonable expectation of success, and that all of the elements of the present invention are not present in the cited prior art.

The present Office Action states in response to such assertions that “the motivation to combine the references is found in the teaching reference as discussed in the above action.” MPEP §2143.01(I) states in part:

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006) (discussing rationale underlying the motivation-suggestion-teaching requirement as a guard against using hindsight in an obviousness analysis). The teaching, suggestion, or motivation must be found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In the present Office Action, there are no “specific factual findings” presented as to where the motivation to combine these references is found. Applicant has not been directed to any teaching, suggestion or motivation, either explicit or implicit, in the references to make such combination in order to accomplish the present invention. Accordingly, it is respectfully submitted that while the Office Action makes the assertion that Claims 2 and 3, and 14 and 15 are “unpatentable over Cianci in view of Wu et al (US 4246909) or Cianci in view of Barnes in view of Wu,” the Office Action fails to establish even a *prima facie* case of obviousness.

In view of the amendments noted above with respect to Claims 1 and 13, Claims 2 and 14 have been cancelled. In view of the noted allowability of Claims 1 and 13, it is respectfully submitted that Claims 3 and 15 are allowable as depending from an allowable base claim.

Accordingly, and in view of the amendment of Claims 1 and 13 and cancellation of Claims 2 and 14 as set forth above, it is respectfully submitted that the rejection of Claims 3 and 15 under 35 U.S.C. §103(a) has been overcome.

4) *Claims 4 and 16*

Examiner's Rejection

Claims 4 and 16 were rejected under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Wu *et al.*, or in view of Ciani *et al.*, in view of Barnes *et al.*, in view of Wu *et al.*, as applied to Claims 2 and 13 above, and further in view of Poncy, U.S. Patent Number 4,165,000. In support of the rejection, the Office Action states:

Claim 4 differs from Ciani in view of Wu in calling for the first end of the cover to define a funnel configuration. Claim 16 differs in calling for the step of defining the funnel. Poncy teaches a medical probe cover having a first end with a flaring or funnel configuration defined by a heat sealing die to facilitate the insertion of the medical probe (Col. 4, lines 18-22). See Fig. 5. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to have a first end with a funnel configuration as taught by Poncy to facilitate insertion of the probe.

Applicant's Argument

The prior rejection has been restated, and an additional combination of reference, to further include Barnes *et al.*, has been cited. While an additional reference has been cited, the rationale is identical to that of the previous Office Action. There has been no rationale provided for the newly cited prior art. Accordingly, the Applicant's prior response is repeated herein by reference.

Notwithstanding the lack of specific rationale in making the above combination of references, it is assumed that the intent of the Office Action was to combine the step of folding the two-ply construction over itself as taught by Barnes *et al.*, prior to sealing thereof. Applicant's remarks above with respect to Barnes *et al.*, are incorporated herein by reference.

In view of the deemed allowability of independent Claims 1 and 13 above, it is deemed that Claim 4 is allowable as depending from allowable base Claim 1, and that Claim 16 is allowable as depending from allowable base Claim 13.

Notwithstanding the deemed allowability of the claims, for reasons set forth in the discussion of the *Cianci et al./Wu et al.*, rejection, it is respectfully submitted that there is no motivation for combining the cited prior art references to accomplish the present invention as set forth in Claims 4 and 16. Even if such motivation were present, there is no reasonable expectation of success, as all of the elements of the present invention are not present in the cited prior art.

Accordingly, and in view of the amendment of Claims 1 and 13 as set forth above, it is respectfully submitted that the rejection of Claims 4 and 16 under 35 U.S.C. §103(a) has been overcome.

5) *Claims 5 and 17*

Examiner's Rejection

Claims 5 and 17 were rejected under 35 U.S.C. §103(a) as being obvious under *Cianci et al.*, in view of Poncy, or *Cianci et al.*, in view of Barnes *et al.*, in view of Poncy. In support of the rejection, the Office Action states:

Claim 5 differs from *Cianci* in calling for the first panel member to extend beyond the second panel. Claim 17 differs in calling for the step of defining the extended portion. Poncy teaches a cover having a first panel 24 that projects beyond the end of the second panel 22 to serve as a guide to facilitate inserting the probe into the sheath (Col. 3, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of *Cianci* to have a first panel extending beyond the second panel as taught by Poncy to facilitate insertion of the probe into the sheath.

Applicant's Argument

The prior rejection has been restated, and an additional combination of reference, to further include Barnes *et al.*, has been cited. While an additional reference has been



cited, the rationale is identical to that of the previous Office Action. There has been no rationale provided for the newly cited prior art. Accordingly, the Applicant's prior response is repeated herein by reference.

Notwithstanding the lack of specific rationale in making the above combination of references, it is assumed that the intent of the Office Action was to combine the step of folding the two-ply construction over itself as taught by Barnes *et al.*, prior to sealing thereof. Applicant's remarks above with respect to Barnes *et al.*, are incorporated herein by reference.

In view of the deemed allowability of independent Claims 1 and 13 above, it is deemed that Claim 5 is allowable as depending from allowable base Claim 1, and that Claim 17 is allowable as depending from allowable base Claim 13.

Accordingly, and in view of the amendment of Claims 1 and 13 as set forth above, it is respectfully submitted that the rejection of Claims 5 and 17 under 35 U.S.C. §103(a) has been overcome.

6) *Claims 6 and 18*

Examiner's Rejection

Claims 6 and 18 were rejected under 35 U.S.C. §103(a) as being obvious under Cianci *et al.*, in view of Gammons *et al.*, U.S. Patent Number 6,224,543, or Cianci *et al.*, in view of Barnes *et al.*, in view of Gammons *et al.* In support of the rejection, the Office Action states:

Claim 6 differs from Cianci in calling for the cover to be partially inverted. Claim 18 differs from Cianci in view of Barnes in calling for the step of inverting the second end. Gammons teaches a sheath having a second end that has been inverted to facilitate movement of the sheath onto the tip of a medical probe (Col. 1, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to be partially inverted as taught by Gammons to facilitate movement of the sheath onto the tip of a medical probe.

### Applicant's Argument

The prior rejection has been restated, and an additional combination of reference, to further include Barnes *et al.*, has been cited. While an additional reference has been cited, the rationale is substantially identical to that of the previous Office Action. There has been no rationale provided for the newly cited prior art. Accordingly, the Applicant's prior response is repeated herein by reference.

Notwithstanding the lack of specific rationale in making the above combination of references, it is assumed that the intent of the Office Action was to combine the step of folding the two-ply construction over itself as taught by Barnes *et al.*, prior to sealing thereof. Applicant's remarks above with respect to Barnes *et al.*, are incorporated herein by reference.

In view of the deemed allowability of independent Claims 1 and 13 above, it is deemed that Claim 6 is allowable as depending from allowable base Claim 1, and that Claim 18 is allowable as depending from allowable base Claim 13.

Accordingly, and in view of the amendment of Claims 1 and 13 as set forth above, it is respectfully submitted that the rejection of Claims 6 and 18 under 35 U.S.C. §103(a) has been overcome.

7) *Claim 7*

### Examiner's Rejection

The examiner rejected Claim 7 under 35 U.S.C. §103(a) as being obvious under Cianci *et al.*, in view of Weaver, U.S. Patent Number 5,667,068. In support of the rejection, the Office Action states:

Claim 7 differs from Cianci in calling for the cover to be fabricated of a material having elastomeric properties. Weaver teaches a protective cover for a medical probe formed of an elastic material so that the cover can protect the delicate probe (Col. 2, lines 61 -66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci

to be formed of an elastic material as taught by Weaver to protect the delicate probe.

#### Applicant's Argument

The prior rejection has been restated. Accordingly, the Applicant's prior response is repeated herein by reference.

In view of the deemed allowability of independent Claim 1 above, it is deemed that Claim 7 is allowable as depending from allowable base Claim 1.

Accordingly, and in view of the amendment of Claim 1 as set forth above, it is respectfully submitted that the rejection of Claim 7 under 35 U.S.C. §103(a) has been overcome.

#### 8) *Claims 8-10*

##### Examiner's Rejection

The examiner rejected Claims 8-10 under 35 U.S.C. §103(a) as being obvious under *Cianci et al.*, in view of *Poncy* and further in view of *Wu et al.* In support of the rejection, the Office Action states:

Cianci discloses a catheter sheath having a first panel member 48a and a second panel member 48b defining a tubular configuration, the first panel being folded over to form a double thickness, and the second panel being folded over to form a double thickness (Col. 3, lines 30-40). See Fig. 2.

10. Claim 8 differs from *Cianci* in calling for the first panel member to extend beyond the second panel. *Poncy* teaches a cover having a first panel 24 that projects beyond the end of the second panel 22 to serve as a guide to facilitate inserting the probe into the sheath (Col. 3, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of *Cianci* to have a first panel extending beyond the second panel as taught by *Poncy* to facilitate insertion of the probe into the sheath.

11. Claim 8 further differs from *Cianci* in view of *Poncy* in calling for in calling for the cover to further comprise a throat. Claim 9 differs in calling for

the width of the throat to be less than [sic] one half of the circumference of the medical probe, Wu teaches a cover 10 for a medical probe having a throat 37 with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

12. Claim 10 differs from the teachings above in calling for the cover to have a funnel configuration. Poncy teaches a medical probe cover having a first end with a flaring or funnel configuration to facilitate the insertion of the medical probe (Col. 4, lines 18-22). See Fig. 5. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to have a first end with a funnel configuration as taught by Poncy to facilitate insertion of the probe.

#### Applicant's Argument

The prior rejection has been restated. Accordingly, the Applicant's prior response is repeated herein by reference.

Claim 8 includes all of the limitations of allowable Claim 1. Accordingly, it is respectfully submitted that, for reasons provided above, Claim 8 is also allowable. Further, it is deemed that Claims 9-12, depending from Claim 8, are each in condition for allowance as depending from an allowable base claim.

Notwithstanding the deemed allowability of the claims, for reasons set forth in the discussion of the Cianci *et al.*/Wu *et al.*/Poncy rejection above, it is respectfully submitted that there is no motivation for combining the cited prior art references to accomplish the present invention as set forth in Claims 8-10. Even if such motivation were present, there is no reasonable expectation of success, as all of the elements of the present invention are not present in the cited prior art.

Notwithstanding the noted allowability of Claim 8 as originally presented, such claim has been amended to include the limitations that the throat is defined within a

region where the first and second panel members define the double thickness in order to provide sufficient resiliency to maintain the cover on the distal end of the medical probe without necessitating further retaining means. It is respectfully submitted that these limitations are not disclosed, anticipated or made obvious by the prior art of record.

Accordingly, in view of the amendment of Claim 8, it is respectfully submitted that the rejection of Claim 8 under 35 U.S.C. §103(a) has been overcome.

9) *Claim 11*

Examiner's Rejection

The examiner rejected Claim 11 under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Poncy and Wu *et al.*, and further in view of Gammons *et al.* In support of the rejection, the Office Action states:

Claim 11 differs from the teachings above in calling for the cover to be partially inverted. Gammons teaches a sheath having a second end that is inverted to facilitate movement of the sheath onto the tip of a medical probe (Col. 1, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to be partially inverted as taught by Gammons to facilitate movement of the sheath onto the tip of a medical probe.

Applicant's Argument

The prior rejection has been restated. Accordingly, the Applicant's prior response is repeated herein by reference.

In view of the deemed allowability of independent Claim 8 above, it is deemed that Claim 11 is allowable as depending from allowable base Claim 8.

Accordingly, and in view of the amendment of Claim 8, it is respectfully submitted that the rejection of Claim 11 under 35 U.S.C. §103(a) has been overcome.

10) *Claim 12*

Examiner's Rejection

The examiner rejected Claim 12 under 35 U.S.C. §103(a) as being obvious under Ciani *et al.*, in view of Poncy and Wu *et al.*, and further in view of Weaver. In support of the rejection, the Office Action states:

Claim 12 differs from the teachings above in calling for the cover to be fabricated of a material having elastomeric properties. Weaver teaches a protective cover for a medical probe formed of an elastic material so that the cover can protect the delicate probe (Col. 2, lines 61-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to be formed of an elastic material as taught by Weaver to protect the delicate probe.

Applicant's Argument

The prior rejection has been restated. Accordingly, the Applicant's prior response is repeated herein by reference.

In view of the deemed allowability of independent Claim 8 above, it is deemed that Claim 12 is allowable as depending from allowable base Claim 8.

Accordingly, and in view of the amendment of Claim 8, it is respectfully submitted that the rejection of Claim 12 under 35 U.S.C. §103(a) has been overcome.

**Summary**

In view of the amendment of Claims 1, 8 and 13, the cancellation of Claims 2 and 14, without prejudice, and the arguments presented herein, it is believed that the above-identified patent application is in a condition for the issuance of a Notice of Allowance. Such action by the examiner is respectfully requested. If, however, the examiner is of the opinion that any of the drawings or other portions of the application are still not allowable, it will be appreciated if the examiner will telephone the undersigned to expedite the prosecution of the application.

Please charge any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 16-1910 (27455.00).

Respectfully submitted,

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